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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/608,774 | 06/27/2003 | Jeffrey Karl Sutton | 101896-0163 | 8137 |
| 21125 | 7590 | 01/24/2006 | EXAMINER | |
| NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | ROGERS, KRISTIN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/608,774 | Applicant(s) SUTTON ET AL. | |
| | Examiner Kristin D. Rogers | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☒ Claim(s) 1-3, 14 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>October 6, 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This communication is in response to Restriction Requirement received December 19, 2005. The Examiner acknowledges Applicant's election of Species I, Claims 1-8, 11-15, and 18, furthermore, upon review of the Restriction Requirement and claims, the Restriction Requirement is withdrawn and claims 1-18 will be considered on their merits.

Specification

1. Claims 1-3, 14 and 18 are objected to because of the following informalities: The omission of the word "the" preceding the phrase "at least one opening" is suggested. Appropriate correction is required.
2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, 11-14, and 17 are rejected under 35 U.S.C. 102(b) as being

Art Unit: 3736

anticipated by Bryan et al (6488636). In regard to claim 1, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. In regard to claim 5, Bryan et al. shows a bone marrow sampling device an inner cannula 16 with a closed distal end, Figure 3. In regard to claim 6, Bryan et al. shows a biological tissue-sampling device with an inner cannula 16 with a plurality of openings 15 in the sidewall. In regard to claim 11, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, and a suction knob 66 on the proximal end of the inner cannula. In regard to claims 12,13 and 14, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, a second inner cannula 24 without openings in the sidewall, and is selectively movable with respect to the outer and inner cannula. In regard to claim 17, Bryan et al. teaches a sampling device with outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall arranged in a helical pattern.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al as applied to claim 1 above and in view of Krueger (20030050574). In regard to claim 2, Bryan et al shows a sampling device with an inner cannula 16 and outer cannula 12 an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan et al. lacks disclosure of the diameter of the withdrawal aperture. Krueger teaches the claimed invention where the openings of the outer and inner cannula create a withdrawal aperture 16 where the size of the openings may vary for the purpose of providing a space large enough to permit encroachment of sampled tissue (page 3 column 1, paragraph 37). It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with withdrawal apertures on the inner and outer cannula where the diameter of the openings can range from 0.5mm to 3mm in order to provide a sampling space for biological material. In regard to claim 3, Bryan et al. doesn't teach the alignment of the inner and outer cannula creating a withdrawal aperture. Krueger teaches the claimed invention where the openings of the outer and inner cannula create a withdrawal aperture in the range of 0.5mm² to 8mm² (page 3, column 1,

Art Unit: 3736

paragraph 37). It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with withdrawal apertures on the inner and outer cannula with a diameter 0.5mm^2 to 8mm^2 as taught by Krueger for the purpose of providing a sampling space for biological material. In regard to claim 7, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan et al. does not disclose the minimum distance between the openings in the sidewall. Krueger teaches a biological tissue biopsy device that shows the openings in the sidewall 16 at least 5mm apart. Therefore, it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with a cannula that has sidewall openings spaced at least 5mm apart as taught by Krueger to meet the structural limitations of the claimed invention. In regard to claim 18, Bryan et al. lacks indicia on the outer and inner cannula. Krueger teaches a biological tissue biopsy device with indicia 17 on the exterior surface of the inner and outer cannula for providing orientation markers (Figures 1 and 4). Therefore, it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with indicia on the outer and inner cannula as taught by Krueger since such modification would provide and indication of the alignment of the inner and outer cannula.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Van Bladel et al. (2003/0093008). Bryan et al. teaches the claimed

sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan et al. lacks disclosure of the dimensions of the outer cannula. Van Bladel et al. teaches a biological tissue biopsy device with an outer and inner cannula, 5 and 20 respectively, where the outer cannula has a diameter of 3mm. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with an outer cannula with a diameter of 3mm as taught by Bladel et al. for the purpose of meeting the structural limitations of 0.7mm to 6mm as stated in the claimed invention.

6. Claims 8 to 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Akerfeldt et al. (5810826). In regard to claims 8, 9, and 10, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan lacks an inner and outer cannula with translational and rotational movement. Akerfeldt et al. teaches a puncturing device comprising an inner cannula 5 and outer cannula 2 with rotational, translational, and a combination of rotational and translational movement, Figure 1 and 5. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with an inner and outer cannula with rotational and translational movement for the purpose

of providing the device with cannula with a combination of rotation and translational movement.


7. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Ritchart et al. (2002/0016555). In regard to claims 15 and 16, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, a second inner cannula 24 without openings in the sidewall, and is selectively movable with respect to the outer and inner cannula. Bryan et al lacks a channel in the sidewall for the delivery of treatment material and automated movement of the inner and outer cannula. Ritchart et al. teaches a biopsy collection device with a channel between the inner and outer cannula with a passage for the purpose of delivering treatment material, Figure 23. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with a channel in the second inner cannula as taught by Ritchart et al. for the purpose of providing a channel for delivering treatment material and automating the movement between the inner and outer cannula.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDR


MAX F. HINDENBURG
SUPERVISOR/PATENT EXAMINER
ELECTRONIC BUSINESS CENTER 3700